

U.S. House and Senate Notification
Tuesday, December 22, 2009

To: Congressional Health Staff

From: Amy Hall
Director, Office of Legislation
Centers for Medicare & Medicaid Services

Re: New Medicare Part D Policy to Ensure Medicare Beneficiaries Receive Prescription Drug Products That Are Properly Listed with the Food and Drug Administration (FDA)

Today, the Centers for Medicare & Medicaid Services (CMS) issued a Fact Sheet for Medicare Part D enrollees to help ensure that beneficiaries receive safe and legally marketed prescription drugs. Effective January 1, 2010, CMS will no longer reimburse Part D sponsors for prescription drugs that are not listed with the FDA. This policy is part of a safety initiative to ensure that Medicare Part D enrollees receive prescription drugs that are properly registered with the FDA.

Most Part D enrollees should experience no difficulty with filling their prescriptions under this policy as only a small number of the affected products were prescribed to Medicare Part D enrollees in 2009. However, to answer questions, CMS is issuing the attached Fact Sheet. This Fact Sheet provides beneficiaries and people who work with beneficiaries with information about filling their prescriptions with FDA listed products. In addition, to minimize beneficiary disruption, CMS has conducted extensive outreach to inform pharmacies, Part D sponsors, wholesalers, and manufacturers of this new policy.

Additional technical information about this new Part D requirement can be found in the 2010 Call Letter available at:

<http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/2010CallLetter.pdf>.

If you have questions, please contact the CMS Office of Legislation. Thank you.